

## VENTOLIN™ RESPIRATOR SOLUTION

10000000072424

Salbutamol

### QUALITATIVE AND QUANTITATIVE COMPOSITION

VENTOLIN Respirator Solution contains 5mg salbutamol, as sulphate, per ml of solution and is supplied in 10 ml and 20 ml bottles.

### PHARMACEUTICAL FORM

Nebuliser solution.

### CLINICAL PARTICULARS

#### Indications

VENTOLIN is a selective  $\beta_2$  adrenoceptor agonist. At therapeutic doses it acts on the  $\beta_2$  adrenoceptors of bronchial muscle, with little or no action on the  $\beta_1$  adrenoceptors of the heart. With its fast onset of action, it is particularly suitable for the management and prevention of attack in asthma.

Bronchodilators should not be the only or the main treatment in patients with severe or unstable asthma. Severe asthma requires regular medical assessment as death may occur. Patients with severe asthma have constant symptoms and frequent exacerbations, with limited physical capacity, and PEF values below 60% predicted at baseline with greater than 30% variability, usually not returning entirely to normal after a bronchodilator. These patients will require high dose inhaled (e.g. >1mg/day beclomethasone dipropionate) or oral corticosteroid therapy. Sudden worsening of symptoms may require increased corticosteroid dosage which should be administered under urgent medical supervision.

Routine management of chronic bronchospasm - unresponsive to conventional therapy.

Treatment of acute severe asthma (status asthmaticus).

#### Dosage and Administration

VENTOLIN has a duration of action of 4 to 6 hours in most patients.

VENTOLIN Respirator Solution is to be used with a respirator or nebuliser, only under the direction of a physician.

The solution must not be injected, or swallowed.

Increasing use of  $\beta_2$  agonists may be a sign of worsening asthma. Under these conditions a reassessment of the patient's therapy plan may be required and concomitant glucocorticosteroid therapy should be considered.

Delivery of the aerosol may be by facemask, 'T' piece or via an endotracheal tube.

Intermittent positive pressure ventilation may be used but is rarely necessary. When there is a risk of anoxia through hypoventilation, oxygen should be added to the inspired air.

As there may be adverse effects associated with excessive dosing, the dosage or frequency of administration should only be increased on medical advice.

As many nebulisers operate on a continuous flow basis, it is likely that nebulised drug will be released in the local environment. VENTOLIN Respirator Solution should therefore be administered in a well-ventilated room, particularly in hospitals when several patients may be using nebulisers at the same time.

#### 1. By intermittent administration

Intermittent treatment may be repeated four times daily.

##### • Adults

VENTOLIN Respirator Solution 0.5-1.0ml (2.5-5.0 milligrams of salbutamol) should be diluted to a final volume of 2.0 or 2.5ml using sterile normal saline as a diluent. The resulting solution is inhaled from a suitably driven nebuliser until aerosol generation ceases. Using a correctly matched nebuliser and driving source this should take about ten minutes.

VENTOLIN Respirator Solution may be used undiluted for intermittent administration. For this, 2.0ml of VENTOLIN Respirator Solution (10.0 milligrams salbutamol) is placed in the nebuliser and the patient allowed to inhale the nebulised solution until bronchodilatation is achieved.

This usually takes three to five minutes.

Some adult patients may require higher doses of salbutamol, up to 10 milligrams, in which case nebulisation of the undiluted solution may continue until aerosol generation ceases.

##### • Children

The same mode of administration for intermittent administration is also applicable to children.

The usual dosage for children under the age of twelve years is 0.5ml (2.5 milligrams salbutamol) diluted to 2.0 or 2.5ml using sterile normal saline as diluent. Some children may however require higher doses of salbutamol up to 5.0 milligrams.

Clinical efficacy of nebulised VENTOLIN in infants under 18 months is uncertain. As transient hypoxaemia may occur, supplemental oxygen therapy should be considered.

#### 2. By continuous administration

VENTOLIN Respirator Solution is diluted using sterile normal saline to contain 50-100  $\mu$ g of salbutamol per ml, (1-2ml solution made up to 100ml with diluent). The diluted solution is administered as an aerosol by a suitably driven nebuliser. The usual rate of administration is 1-2 milligrams per hour.

#### Contraindications

VENTOLIN Respirator Solution is contraindicated in patients with a history of hypersensitivity to any of its components.

Although intravenous VENTOLIN and occasionally VENTOLIN tablets and VENTOLIN suppositories are used in the management of premature labour uncomplicated by conditions such as placenta praevia, ante-partum haemorrhage or toxemia of pregnancy, inhaled VENTOLIN presentations are not appropriate for managing premature labour. VENTOLIN presentations should not be used for threatened abortion.

#### Warnings and Precautions

The management of asthma should normally follow a stepwise programme, and patient response should be monitored clinically and by lung function tests.

Increasing use of short-acting inhaled  $\beta_2$  agonists to control symptoms indicates deterioration of asthma control. Under these conditions, the patient's therapy plan should be reassessed. Sudden and progressive deterioration in asthma control is potentially life threatening and consideration should be given to starting or increasing corticosteroid therapy. In patients considered at risk, daily peak flow monitoring may be instituted.

VENTOLIN Respirator solution must only be used by inhalation, to be breathed in through the mouth, and must not be injected or swallowed.

Patients receiving treatment at home with VENTOLIN Respirator Solution must be warned that if either the usual relief is diminished or the usual duration of action reduced, they should not increase the dose or its frequency of administration, but should seek medical advice.

VENTOLIN Respirator Solution should be used with caution in patients known to have received large doses of other sympathomimetic drugs.

VENTOLIN should be administered cautiously to patients with thyrotoxicosis.